



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,015	05/15/2002	Masayoshi Maki	56687(71526)	7186

21874 7590 09/23/2005

EDWARDS & ANGELL, LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER
----------

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
----------	--------------

1618

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/030,015

Applicant(s)

MAKI ET AL.

Examiner

Blessing M. Fubara

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 7 is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, amendment and arguments filed 07/18/05. Claims 6-11 and new claims 12 and 13 are pending.

#### ***Claim Rejections - 35 USC § 102***

1. The rejection of claims 6-11 under 35 U.S.C. 102(e) as being anticipated by Horino et al. (US 5,820,878) is withdrawn because the consisting essentially of language excludes crotamiton, a solubilizer for the hormones, from the preparation and applicants argument as it regards the presence of the solubilizing agent, crotamiton, is persuasive.
2. The rejection of claims 6-11 under 35 U.S.C. 102(a) as being anticipated by Horino et al. (US 5,820,878) is withdrawn for the same reasons above and applicants argument regarding the presence of the solubilizer crotamiton is persuasive.

The preparation of claim 6 consists essentially of a base polymer, norethisterone, estradiol, a softener and an adhesive resin. However, claim 8 requires a solubilizing agent, claims 11-13 further requires the presence of softener and adhesive resin with the base polymer (claim 11), and antioxidant in claims 12 and 13. These ingredients are excluded from the claims 6 and 8 where the preparation consists essentially of.

#### ***Claim Rejections - 35 USC § 103***

3. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horino et al. (US 5,830,878).

Hirano discloses a percutaneous adhesive patch (abstract; column 2, line 12; column 3, lines 54, 62 and 63) and the adhesive patch comprises softening agents such as liquid paraffin, polybutene, castor oil, cottonseed oil, palm oil, coconut oil and process oil (column 2, lines 58-

Art Unit: 1618

6%. The patch further comprises additives such as tackifiers and the tackifiers that can be included in the patch preparation are saturated alicyclic hydrocarbon resins, rosin esters, alicyclic hydrocarbons, terpene hydrogenated resins and hydrogenated rosin esters (column 3, lines 22-2%). The patch contains at least two hormones, estrogen and luteal hormones with estradiol as the preferred estrogen and luteal hormones selected from the group consisting of progesterone, hydroxyprogesterone caproate, medroxyprogesterone acetate, dydrogesterone, chlormadinone acetate, ethisterone, dimethisterone, norethisterone, norethisterone acetate, norethisterone enanthate, ethynodiol acetate, megestrol acetate and allylestrenol (column 2, lines 14-19). Estrogen and the luteal hormones are present in amounts of 0.01 to 10% and with the luteal hormone present in about 1 to 5 times that of the estrogen (column 2, lines 20-2%). Tackifier is present in amount of 0-40% by weight of the total amount of the preparation (column 3, lines 36-45) while the softening agent is present in amounts of 10-70% by weight of the total preparation (column 3, line 13). One of the essential ingredients of the patch is a polymer base that is styrene-butadiene-styrene block copolymer or styrene-isoprene-styrene block copolymer (column 2, lines 30-43) in amounts of 20 to 90% (column 3, line 5). The composition of Hirano may further contain polyisobutylene (Example 23) and although, estradiol in Example 23 is 0.50%, Example 23 is an exemplification of one of the embodiments since Hirano discloses that estradiol in the composition is in amounts of 0.1% to 10% (column 2, lines 20 and 21).

In example 13, the styrene-isoprene-styrene block copolymer is 287, the liquid paraffin, which is a softener is 41% and rosin ester tackifier is 25%. In examples 15 and 16, the amount of styrene-isoprene-styrene block copolymer is 20 and 29% respectively, amount of the liquid paraffin softener is 33 and 30% respectively and the tackifier is 36 and 20% respectively. While

Art Unit: 1618

the amount of estradiol is disclosed in column 2, lines 20-26 to be from 0.01 to 10%, Examples 13, 15, 16 disclose the amounts of estradiol to be 1%, 1% and 0.5% and these amounts are not greater than or are not more than 2%. New claims 12 and 13 require the presence of antioxidant. Examples 1, 10, 12 and 14 of Horino contain butylhydroxytoluene.

Claim 8 now requires the presence of a solubilizer and Horino discloses crotamiton solubilizer. The solubilizing agent of Horino differs from the polyisobutylene solubilizing agent. One solubilizing agent can be used in place of the other. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the adhesive patch of Horino where the solubilizing agent is crotamiton. One having ordinary skill in the art would know how to substitute one solubilizing agent for another with the expectation that solubilizer being substituted with would solubilize the hormones.

4. Claims 8-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al. (US 5,725,874).

Oda discloses percutaneously absorbable preparations that comprise 20% styrene-isoprene-styrene block copolymer, polyisobutylene, liquid paraffin, rosin ester derivative, and 1% norethisterone (examples 44 and 45). The rosin ester derivative is 17% and 30% examples 44 and 45 respectively. Liquid paraffin, is 47% and 25% in examples 44 and 45 respectively. In examples 40 and 41, estradiol is the hormone active agent. Examples 40 and 41 disclose compositions containing estradiol and Example 44 discloses norethisterone containing composition and these Examples also contain polyisobutylene. 1% estradiol is not more than 2% estradiol. 3-1-menthoxy-propane-1,2-diol (abstract) is a solubilizer and claim 8 now requires the presence of a solubilizer and one solubilizer can be substituted with another.

Art Unit: 1618

Although Oda does not disclose a composition that contains both estradiol and norethisterone, Oda discloses individual compositions that contain estradiol and norethisterone. And "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. ...[T]he idea of combining them flows from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 198%). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the individual compositions that contain estradiol and norethisterone according to Oda. One having ordinary skill in the art would have been motivated to combine the two compositions in one composition with the expectation that the resultant composition that contains both estradiol and norethisterone would be effective for the same purpose as the individual compositions. In re Kerkhoven.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is a claim that consists essentially of a base polymer, norethisterone, estradiol, a softener and an adhesive resin. Claim 11 now contains softener adhesive resin in the base. It is not clear how a base that is a styrene-isoprene-styrene block copolymer would contain a softener and an adhesive that materially affects the base polymer as required by claim 6.

Art Unit: 1618

Claims 12 and 13 requires antioxidant while claim 6 excludes antioxidant and the inclusion of antioxidant in the preparation of claim 6 in claims 12 and 13 is indefinite.

***Response to Arguments***

Applicants' argument with respect to crotamiton and Horino is persuasive for claims 6 and 7. But the presence of the solubilizing agent in claim 8 renders the claims obvious in view of Horino since the crotamiton solubilizing agent can be substituted with another solubilizing agent, which in claim 8 is polyisobutylene.

Applicants' argument with respect to 3-1-menthoxy-propane-1,2-diol solubilizing agent and Oda is persuasive for claims 6 and 7. But the presence of the solubilizing agent in claim 8 continues to render obvious these claims over Oda since one solubilizing agent can be substituted with another.

Claims 6 and 7 are patentable over the cited prior art because Horino discloses crotamiton solubilizing agent that is excluded by claim 6; Oda discloses 3-1-menthoxy-propane-1,2-diol solubilizing agent tat is excluded by claim 6.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1618

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara  
Patent Examiner  
Tech. Center 1600

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECH. CENTER 1600